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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,082	09/24/2001	Wei-Sing Chu	2313-113	1159
6449	7590	02/22/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/869,082	Applicant(s) CHU, WEI-SING	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-26 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-26 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response to the office action and the amendment filed on January 6, 2005 has been entered.

Priority

2. This instant application filed on 9/24/2001 is a 371 of PCT/US99/30519 filed on 12/22/1999, which is a CIP of 09/219, 443 filed on 12/23/1998, which is PAT 6,703,247.

Upon reviewing the parent application 09/219,443, which is Patent 6,703,247, it is noted that the instant application contains new matter that is not present in the parent application (examples 9 and 10 of the instant application disclosing a cover slip with concave wells and a method for processing biological samples on slides are not supported by the parent application 09/219, 413) and hence this application is not entitled to claim the priority benefit to the US non-provisional 09/219,443.

Status of the Application

3. Claims 20-25 are amended. New claim 44 is added. Claims 1-19, 27-43 are cancelled. Claims 20-26 and 44 are pending. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL necessitated by the amendment. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note: the limitation “having a known volume is interpreted as a volume that a concave well can enclose based on concave well dimensions. Since the instant claims do not recite any defined volume of the known volume, the broad scope of the term “known” is interpreted as having any volume that the concave well can enclose within its capacity (degree of concavity) limits.

Claims 20, 22-23, 25, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Atwood et al. (USPN 5,364,790).

Regarding Claim 20, Atwood teaches an apparatus comprising:

a microscope slide (see col. 7, line 37-38);

a cover slip having a concave well disposed on said slide (see col. 7, line 38-41. line 64-67, col. 8, line 1-3);

said concave well having a known volume wherein said concave well encloses said known volume when placed onto a microscope slide (see col. 7, line 66-67, col. 8, line 1-3, wherein volume about 10 microliters is a known volume that the concave well encloses when placed onto said slide, see also claim 4 on col.20).

Regarding Claims 22-23, Atwood teaches that the apparatus further comprises an insert (seal ring integral with cross beams) sandwiched between a portion of said cover slip and said microscope slide, that comprises sample (control sample) (see col. 8, line 37-67) col. 17, line 13-63);

Regarding Claim 25, 44, Atwood teaches a method and system for performing an assay (e.g., a PCR reaction) on a biological sample on a microscope slide, comprising, a) placing a

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biological sample on a microscope slide (see col. 6, line 5-9, col. 21, line 33-36); b) placing the cover slip of on said microscope slide (see col. 6, line 9-10, col. 21, line 38-39); allowing water, buffer or reagent to flow into the known volume between said microscope slide and said cover slip and allowing a reaction to occur (see col. 6, line 10-26, col. 21, line 40-48). Thus the disclosure meets the limitations in the instant claims.

Applicant's Arguments

Applicant argues that Atwood “neither teaches, discloses, nor suggest a concave cover slip having a known volume as recited in the instant amended claim 20 and 25. *See* Applicants remarks on page 4. Applicant also argues that the cover of Atwood has no known volume, rather has a range of volumes to accommodate the range of volumes of reagent and argue that the volume depends on the compliant cover member.

See Applicants remarks on page 4-5. Applicant also argues that in the instant invention the volume of reagent that will be retained in the well need not be measured before hand, rather, only a volume of reagent substantially equal to the known volume of the concave well will be retained in the concave well.

Response to Applicant's Arguments

Applicant's arguments have been considered, but are not persuasive for the following reasons. First, Atwood teaches concave well having known volume as discussed in the above rejection (see claim 4 of Atwood disclosure). Second, the broad limitation “known volume” in the instant claims do not exclude the range of known volumes that a concave well can hold within its dimensions as taught by Atwood, particular because the instant claims do not recite any specific volume. Third, giving the claims their broadest reasonable interpretation, the

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limitation “concave well having known volume” do not exclude that the known volume depends on the degree of concavity or the dimensions of the concave well and the capacity that it can hold.

Finally, in response to Applicant’s arguments directed to “the volume need not be measured beforehand, rather, it is equal to the known volume of the concave well”, Examiner noted that the Applicant contradicts the statement with the earlier arguments on page 4. It is noted based on the final argument, that the known volume is based on the known dimensions of the concave well. Since Atwood teaches such known volume, the arguments presented by the Applicant's arguments are found unpersuasive. Therefore the rejection is maintained for claims 20, 22-23, 25 and rewritten as above to include the claim limitations of claim 44.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood et al. (USPN 5,364,790) as applied to claims 20, 22-23, 25 and 43 above, and further in view of Pan et al. (WO 97/07241).

The teachings of Atwood are presented above. Specifically, Atwood teaches a concave cover slip, which can be used in a PCR reaction. Atwood does not teach a cover slip comprising reagents dried thereon.

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However, drying reagents onto cover slips is well known in the art. For example, Pan teaches a PCR reaction comprising attaching a tissue section onto a cover slip, drying the tissue, and then adding reagents to carry out the PCR reaction. *See* pages 3-10 and example 4. Pan teaches that the tissue can be attached to the cover slip, rinsed in alcohol and allowed to dry prior to PCR. *See* page 5. Pan also teaches that prior to the attachment of the tissue, the cover slip can have a pre-dried adhesive on the surface of the cover slip (page 9), or can simply be dried overnight (page 18). Pan teaches the above methods provided a simplified method that is faster, more accurate and less expensive than previous methods of carrying out PCR. *See* pages 1-3.

Accordingly, in view of the teachings of Pan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Atwood so as to have dried reagents on a cover slip, in order to have achieved the benefit of providing a more efficient, accurate and less expensive method of carrying out PCR.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood et al. (USPN 5,364,790) as applied to claims 20, 22-23, 25 and 43 above, and further in view of Kuan et al. (USPN 6,181,811).

The teachings are Atwood are presented above. Atwood does not teach a cover slip comprising a barcode or text.

However, the use of barcodes or text is a well-known tool for identifying slides or cover slips of interest. For example, Kuan teaches that barcodes can be used for identification purposes in automated systems. *See* Figs. 8a and b and cols. 14-15.

Accordingly, in view of the teachings of Kuan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the coverslip of

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Atwood so as to have labeled the coverslip with a barcode or text, in order to have achieved the benefit of providing an effective means for identifying a sample in an automated system.

Applicant's Arguments with respect to the rejections of Atwood in view of Pan or Kuan

Applicant argues that the claims 21, 26 as rejected over Atwood in view of Pan et al. and claim 24 as rejected over Atwood in view of Kaun et al. depend on the instant amended claim 20, which distinguishes the instant invention from that of Atwood and therefore are not obvious.

Response to Applicant's Arguments

Applicant's arguments have been considered, but are not persuasive for the reasons set forth above in the "Response to Applicant's Arguments" under the 102 rejection of Atwood. Accordingly, because Atwood teaches and discloses a concave cover slip having a known volume and encloses said known volume when placed onto a microscope slide, Applicants arguments are not persuasive.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru
Examiner
Art Unit 1637


JEFFREY FREDMAN
PRIMARY EXAMINER

2/15/05